

### **DETAILED ACTION**

Applicant's amendment filed May 16, 2011 has been received and entered. Claims 2 and 10-12 have been cancelled, and new claim 44 has been added. Accordingly, claims 1, 3-9 and 13-44 are pending in the instant application, of which claims 4, 6, 18-43 have been withdrawn from further consideration as being drawn to non-elected inventions.

### ***Claim Rejections - 35 USC § 112***

1. The rejection of claims 15-16 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions, does not reasonably provide enablement for compositions which afford "protection" is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants are asserting that the claims have been amended to recite "comprising an immunogen which affords protection against pathogens responsible for diarrhoeal disease in humans." Applicants further assert that support for this claim is found in the specification page 143, which sets forth "protection as assessed by reduction of the bacterial load, was observed with the penta, deca and petadecasaccharides conjugates."

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments equate reduction of bacterial load as equivalent to protection. However, no such simply analogy can be made. For example, current anti-viral therapy can reduce HIV viral loads by 90% or more, however no antiviral therapy has ever been created to date that can afford "protection." Protection "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Applicants claims remain enabled for a composition that "reduces bacterial loads" or induces an "immune response" however the current claim language of "affords protection" remains non-enabled for the reasons set forth above.

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir 1999).

Katritch et al (US Publication 2003/0235818) set forth that "Shigella infections are a major problem in refugee and military populations. The current would political climate

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underscores the inherent need for an effective vaccine in crisis refugee management. It should be ***emphasized*** that as yet, ***no good Shigella vaccine is available.***” (See detailed paragraph 114; Emphasis added).

Protection “must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough.” In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Given the lack of guidance, and the unpredictable nature of the invention, one of skill in the art would be forced into excessive experimentation in order to practice the instantly claimed invention.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 14-15, for the phrase "such as" is withdrawn in view of Applicants amendment.

3. The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the use of the phrase “derivative” is withdrawn in view of Applicants amendment.

***Claim Rejections - 35 USC § 102***

4. The rejection of claims 1-3, 5, 7-9, and 12-17 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Polotsky et al is withdrawn in view of Applicants amendment.

The following new grounds of rejection are applied to the amended claims:

***Claim Rejections - 35 USC § 112***

5. Claims 13-16 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-16 and 44 depend on "claims 1-9." However, claim 2 has been cancelled by Applicants. Accordingly, one of skill in the art would be unable to determine the metes and bounds of claims which depend on cancelled claims. Appropriate correction is required.

6. Claims 14-16 and 44 are rejected under 35 U.S.C. 112, fourth paragraph, for failing to recite each and every limitation of the independent claim as not further limiting.

Claims 14-16 and 44 recite "wherein said oligo or polysaccharide is a pentasaccharide or a multimer thereof. However, the independent claim 1 already sets forth that the oligo or polysaccharide has an n value of 2 or 3. Accordingly the minimum length of the saccharide is AB(E)CDAB(E)CD when n=2. This decasaccharide is larger

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than a "pentasaccharide." Accordingly, the limitation found in claim 14 does not further limit, and in fact incorrectly broadens the subject matter of independent claim 1.

Appropriate correction is required.

Claims 1, 3, 5, 7-9, 17 are allowed.

In view of allowed independent claim 1, withdrawn claims 4 and 6 are rejoined, and also allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571)272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Mark Navarro/  
Primary Examiner, Art Unit 1645  
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